IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHROMADEX, INC. and TRUSTEES OF DARTMOUTH COLLEGE, Plaintiffs, v. ELYSIUM HEALTH, INC., Defendant.	**C.A. NO.: _____** **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ChromaDex, Inc. ("ChromaDex") and Trustees of Dartmouth College ("Dartmouth"), by and through their undersigned counsel, file this Complaint against Defendant Elysium Health, Inc. ("Elysium"), and allege with knowledge regarding their own acts and on information and belief as to other matters, as follows:

NATURE OF THE ACTION

1. ChromaDex and Dartmouth bring this action to compel Elysium to (i) cease infringement of U.S. Patent No. 8,197,807 ("the '807 patent") and U.S. Patent No. 8,383,086 ("the '086 patent") and (ii) compensate them for Elysium's willful infringement of those patents.

2. A true and correct copy of the '807 patent is attached as Exhibit A.

3. A true and correct copy of the '086 patent is attached as Exhibit B.

4. ChromaDex is the exclusive licensee under the '807 and '086 patents in various fields, including dietary supplements. Dartmouth is the assignee of all right, title, and interest in the '807 and '086 patents.

5. ChromaDex has been, and continues to be, the industry leader in the science, research, and development of isolated nicotinamide riboside ("NR"), a unique form of vitamin B3 for use in oral dietary supplements, among other things.

THE PARTIES

6. Plaintiff ChromaDex is a corporation organized under the laws of the State of California and having a principal place of business at 10005 Muirlands Boulevard, Suite G, Irvine, California 92618.

7. ChromaDex is a global nutraceutical company with products focused on proprietary health, wellness, and nutritional ingredients that address the dietary supplement, functional food, beverage, skin care, and potentially pharmaceutical markets. ChromaDex protects these products through, *inter alia*, its intellectual property ("IP") portfolio, including patents. ChromaDex has expended, and continues to expend, significant resources to develop, acquire, and license this IP portfolio, which includes the '807 and '086 patents.

8. ChromaDex sells the TRU NIAGEN® dietary supplement to distributors, including Healthspan LLC, a wholly-owned subsidiary of ChromaDex Corporation, the parent of ChromaDex. Healthspan sells TRU NIAGEN® directly to consumers.

9. Plaintiff Dartmouth is a non-profit educational research institution existing under the laws of the State of New Hampshire and having a principal place of business at 6066 Development Office, Hanover, New Hampshire, 03755.

10. Dr. Charles M. Brenner, the inventor of the '807 and '086 patents, was an Associate Professor (2003–2007) and Professor (2007–2009) of Genetics and of Biochemistry at the Dartmouth Medical School. Dr. Brenner assigned his inventions as disclosed in the '807 and '086 patents to Dartmouth.

11. Defendant Elysium is a corporation organized under the laws of the State of Delaware and having a principal place of business at 934 Broadway, Floor 2, New York, New York, 10013.

12. Defendant Elysium makes or has made, uses or has used, offers for sale or has offered for sale, and sells or has sold the dietary supplement BASIS® through the internet to customers nationwide, including, on information and belief, to residents of Delaware. BASIS® is a composition that comprises isolated NR and is said to increase NAD+ biosynthesis upon oral administration.

JURISDICTION AND VENUE

13. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*, including but not limited to 35 U.S.C. §§ 271 and 281–85.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

15. This Court has personal jurisdiction over Elysium consistent with the Due Process Clause of the U.S. Constitution and the Delaware Long-Arm Statute.

16. Elysium is a corporation organized under the laws of the State of Delaware with a registered agent for service of process in the State of Delaware: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware, 19808. Therefore, Elysium resides within, and has consented to, personal jurisdiction within this District.

17. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b), at least because Elysium resides in this district by virtue of its organization under the laws of the State of Delaware.

BACKGROUND

18. ChromaDex is an innovator and leader in the field of NR technology. It sells to consumers, through Healthspan and other distributors, the TRU NIAGEN® oral dietary supplement. ChromaDex also sells the dietary ingredient NIAGEN® NR to customers in the United States and internationally. Some of those customers formulate the NIAGEN® NR into dietary supplements and sell those supplements to customers in the United States. TRU NIAGEN® and NIAGEN® comprise isolated NR. In November 2015, ChromaDex received its first acknowledgement from the U.S. Food and Drug Administration ("FDA") on ChromaDex's New Dietary Ingredient (NDI) submission for NIAGEN®. It received a second acknowledgement from FDA for ChromaDex's NDA submission for NIAGEN® in March 2018. NIAGEN® was generally recognized as safe by an independent panel of expert toxicologists, and in August 2016, the FDA issued a Generally Recognized As Safe (GRAS) No Objection Letter.

19. ChromaDex has expended, and continues to expend, significant resources to design, conduct, sponsor, fund, and supply the NIAGEN® dietary ingredient products for clinical trials and studies to investigate the additional potential benefits of NR on various human structures and functions, cells, organs and tissues, diseases, indications, and conditions. These include mild cognitive impairment, epilepsy, neuropathies, neurodegenerative diseases, neurological injury, obesity, pain, muscular health, aging, metabolic health, mitochondrial myopathies, cardiovascular health, cognitive health, osteoporosis, cancer, intestinal diseases, kidney disease, lactation, and liver function.

20. Beginning in February 2014, under a Supply Agreement that was amended in 2016, ChromaDex provided to Elysium Health LLC (and then to its successor Elysium)

NIAGEN® for the purpose of Elysium making and selling a dietary supplement containing NIAGEN®. Elysium marketed this dietary supplement under the trademark BASIS®.

21. Contemporaneously with the February 2014 Supply Agreement, under a Trademark License and Royalty Agreement, ChromaDex granted Elysium the right to use and display ChromaDex trademarks and logos, and to list ChromaDex patents, patent applications, and other intellectual property and proprietary information on dietary supplements Elysium sold containing NIAGEN®. Under that Agreement, Elysium marked its BASIS® product, *inter alia*, as being protected under the ’807 and ’086 patents.

22. At various times in 2015 and 2016, Elysium ordered and ChromaDex supplied various amounts of NIAGEN® to Elysium, who formulated it to produce dietary supplements, which it marketed as its BASIS® product. While Elysium paid ChromaDex for the first two of those orders, it did not pay for its last order (June 2016). As a result, ChromaDex terminated the Supply Agreement (as amended) effective February 2, 2017 and provided notice to Elysium of that termination.

23. On information and belief, Elysium began to make and sell its BASIS® dietary supplement using isolated NR from alternative sources no later than July 2017 with full knowledge that this product falls within the claims of the ’807 and ’086 patents . Despite switching to an alternative source of isolated NR, on information and belief, Elysium continues to promote and market its BASIS® dietary supplement with reference to the results of clinical trials and studies conducted using BASIS® formulated from ChromaDex-sourced NIAGEN® NR.

THE PATENTS-IN-SUIT

24. Dr. Brenner, the inventor of the ’807 and ’086 patents, discovered that isolated NR is a new and unique form of vitamin B3 that provides an independent and theretofore

unknown route (the nicotinamide riboside kinase ("Nrk") pathway) to the production of oxidized nicotinamide adenine dinucleotide (NAD+) in humans, a coenzyme vital to cellular function. NAD+ is essential for life in all organisms, both as a co-enzyme for oxidoreductases and as a source of ADPribosyl groups used in various reactions and processes in the body, including those that slow aging. NAD+ is central to energy metabolism, the lack of which may lead to mitochondrial dysfunction, which can affect most cellular systems in the body. NAD+ levels decrease as people age. NAD+ levels also decrease as the result of physiological stresses, such as those that result from alcohol consumption, excess nutrients, or sun exposure. NAD+ deficiency is also implicated in various conditions such as congenital malformations, neuropathies, and diabetes.

25. Although other forms of Vitamin B3—e.g., nicotinamide and nicotinic acid (niacin)—were known, Dr. Brenner discovered that isolated NR could be formulated for oral administration and administered orally in a way that enhances NAD+ biosynthesis more effectively than those other forms of Vitamin B3, while also avoiding their undesirable side effects, such as flushing.

26. The '807 and the '086 patents are the result of Dr. Brenner's work and discoveries.

27. The claims of the '807 patent incorporate Dr. Brenner's inventions, at least in the context of isolated NR, its formulation into an oral composition, and its use to increase NAD+ biosynthesis upon oral administration. Individually and together, those inventions were not well understood, routine, or conventional at the time of Dr. Brenner's inventions.

28. The claims of the '086 patent incorporate Dr. Brenner's inventions, at least in the context of NR in admixture with a carrier, its formulation into an oral composition, its isolation

from a natural or synthetic source, and its use to increased NAD+ biosynthesis upon oral administration. Individually and together, those inventions were not well understood, routine, or conventional at the time of Dr. Brenner's inventions.

COMPOSITIONS COMPRISING ISOLATED NR AND PHARMACEUTICAL COMPOSITIONS COMPRISING NR

29. Compositions comprising isolated NR and pharmaceutical compositions comprising NR are not compositions found in nature, nor do they have the inherent properties of any naturally occurring NR composition. Instead, compositions comprising isolated NR and pharmaceutical compositions comprising NR, when formulated in accordance with the teachings of the '807 and '086 patents, increase NAD+ biosynthesis upon oral administration. Isolated NR and pharmaceutical compositions comprising NR do not occur in nature.NR, as it exists in nature (in some foods), is bound to other molecules. It cannot be isolated in that bound form or formulated into oral or pharmaceutical compositions to be bioavailable, let alone to increase NAD+ biosynthesis. Isolated NR and pharmaceutical compositions comprising NR are thus new and non-obvious forms of NR, formulated in new and non-obvious compositions, to achieve new and unexpected benefits that are not possible with the bound form of NR as it exists in nature.

30. Upon information and belief, Elysium promotes and markets the accused BASIS® dietary supplement as different in its composition and distinct in its effects from naturally-occurring unisolated NR. Among other things, Elysium promotes and markets its product based on the benefits of orally administering isolated NR on NAD+ biosynthesis.

31. In Petitions seeking institution of *Inter Partes* Review ("IPR") proceedings before the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office challenging the '807 and the '086 patents, Elysium relied on the testimony of Joseph A. Baur, Ph.D., whom Elysium described as an expert in the field of the inventions of the '807 and '086

patents. Trial was not instituted as to any of the claims of the ’807 patent, with the PTAB finding that Elysium had failed to establish a reasonable likelihood of prevailing because it had not adduced evidence that isolated NR was present either expressly or inherently in the prior art. IPR2017-01796, Final Decision at 8–11 (Jan. 18, 2018) (Exhibit C). Trial was initially instituted as to claims 1 and 3–5 of the ’086 patent. Trial was not initially instituted as to claim 2 for the same reason that trial was not instituted for the claims of the ’807 patent—i.e., because Elysium had failed to establish a reasonable likelihood of prevailing because it had not adduced evidence that isolated NR was present either expressly or inherently in the prior art. IPR2017-01795, Decision, at 13–14 (Jan 29, 2018) (Exhibit D). As a result of *SAS Institute Inc. v Iancu*, 138 S.Ct. 1248 (2018), however, the January 29, 2018 decision instituting trial was modified to include claim 2. Conduct of the Proceeding at 2 (Apr 27, 2018) (Exhibit E). The decision that Elysium had failed to establish a reasonable likelihood of prevailing on claim 2 was not modified.

32. In IPR 2017-01795, Dr. Baur on cross examination, testified that the NR that is found in nature (specifically, in milk) is bound to other molecules and that it is not known whether this binding inactivates the NR. IPR2017-01795, Ex. 2003, Deposition Transcript of Joseph A. Bauer, Ph.D., at 13, 37–38 (Exhibit F). He also testified that it is unknown whether the NR in milk contributes to NAD+ biosynthesis. *Id.* at 15–16, 47. By contrast, he testified that it is established that when taken orally, isolated NR does enhance NAD+ biosynthesis. *Id.* at 48–49.

COUNT I:
(JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 8,197,807 BY ELYSIUM)

33. Plaintiffs reallege and incorporate by reference paragraphs 1-2, 4-27 and 29-32, inclusive, as if fully set forth herein.

34. The United States Patent and Trademark Office duly and legally issued the ’807 patent to Dartmouth on June 12, 2012.

35. On information and belief, the ’807 patent is valid, enforceable, and currently in full force and effect.

36. Claim 1 of the ’807 patent recites:

> A composition comprising isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic acid, or nicotinamide, wherein said combination is in admixture with a carrier comprising a sugar, starch, cellulose, powdered tragacanth, malt, gelatin, talc, cocoa butter, suppository wax, oil, glycol, polyol, ester, agar, buffering agent, alginic acid, isotonic saline, Ringer's solution, ethyl alcohol, polyester, polycarbonate, or polyanhydride, wherein said composition is formulated for oral administration and increases NAD+ biosynthesis upon oral administration.

37. On information and belief, Elysium’s BASIS® product infringes at least claim 1 of the ’807 patent.

38. Elysium’s BASIS® product is made, used, and sold in a capsule form.

39. Each capsule of BASIS® contains a composition comprising isolated NR. The NR is in combination with one or more of tryptophan, nicotinic acid, or nicotinamide.

40. Each capsule of BASIS® comprises isolated NR in admixture with a carrier as specified in the ’807 patent. Elysium represents to the public that each capsule of BASIS® comprises microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica.

41. BASIS® is formulated for oral administration.

42. Elysium represents to the public that BASIS® increases NAD+ biosynthesis in the body upon oral administration.

43. On information and belief, Elysium has been, and is still, knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more

claims of the ’807 patent, including at least claim 1, by making, having made, using, selling, having sold, offering to sell and/or importing the BASIS® product in or into the United States, without authority. Thus, Elysium is liable for its infringement of the ’807 patent in violation of 35 U.S.C. § 271(a).

44. On information and belief, Elysium has been, and is still, knowingly and intentionally inducing infringement, literally and/or under the doctrine of equivalents, of one or more claims of the ’807 patent, including at least claim 1, by actively encouraging others to make, have made, use, offer for sale, sell, have sold, and/or import the BASIS® product in or into the United States, without authority. For example, on information and belief, Elysium has actively and knowingly encouraged and facilitated, and continues to actively and knowingly encourage and facilitate, others to directly infringe the ’807 patent, including at least claim 1, by instructing, directing, and/or advising others how to administer and use BASIS® to increase NAD+ biosynthesis upon oral administration. Thus, Elysium is liable as an active inducer of infringement of the ’807 patent in violation of 35 U.S.C. § 271(b).

45. On information and belief, Elysium has been, and is still, knowingly and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the ’807 patent, including at least claim 1, by making, having made, having sold, using, selling, offering to sell and/or importing the BASIS® product in or into the United States, without authority. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that the BASIS® product is especially made or adapted for use in an infringement of the ’807 patent, that the BASIS® product includes a material component for use in practicing the ’807 patent, and that the BASIS® product is not a staple article or commodity of

commerce suitable for substantial non-infringing use. Thus, Elysium is liable for its infringement of the ’807 patent in violation of 35 U.S.C. § 271(c).

46. On information and belief, Elysium’s infringement of the ’807 patent has been willful, intentional, and deliberate. On information and belief, Elysium is and has been aware of the ’807 patent and knows that the BASIS® product falls within the claims of the ’807 patent. Elysium knew or should have known of the ’807 patent at least as early as February 2014. At that time, it entered into a Supply Agreement and Trademark License and Royalty Agreement with ChromaDex, both of which related to ChromaDex’s NIAGEN® and made reference to the ’807 patent. As recently as 2017, Elysium continued to mark its BASIS® product with the ’807 patent, showing an awareness that the ’807 patent covered its BASIS® product. Healthspan has also provided notice to Elysium of the ’807 patent by marking the TRU NIAGEN® dietary supplements that it obtains from ChromaDex pursuant to 35 U.S.C. § 287(a). Third parties, who formulate dietary supplements under their own label using NIAGEN® NR obtained from ChromaDex, also provide notice to Elysium of the ’807 patent by marking those dietary supplements pursuant to 35 U.S.C. § 287(a). In addition, the filing of this Complaint provides actual notice to Elysium of the ’807 patent under 35 U.S.C. § 287.

47. Plaintiffs have been damaged by the infringing acts of Elysium and will continue to be damaged unless this Court enjoins Elysium from these actions.

COUNT II:
(JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 8,383,086 BY ELYSIUM)

48. Plaintiffs reallege and incorporate by reference paragraphs 1, 3-26, and 28-32, inclusive, as if fully set forth in this paragraph.

49. The United States Patent and Trademark Office duly and legally issued the ’086 patent to Dartmouth on February 26, 2013.

50. On information and belief, the ’086 patent is valid, enforceable, and currently in full force and effect.

51. Claim 2 of the ’086 patent recites:

> A pharmaceutical composition comprising nicotinamide riboside in admixture with a carrier, wherein said composition is formulated for oral administration … wherein the nicotinamide riboside is isolated from a natural or synthetic source.

52. On information and belief, Elysium’s BASIS® product infringes at least claim 2 of the ’086 patent.

53. Elysium’s BASIS® product is made, used, and sold in a capsule form.

54. Each capsule of BASIS® contains a composition comprising isolated NR.

55. The NR in each capsule of BASIS® is isolated from a natural or synthetic source.

56. Each capsule of BASIS® comprises isolated NR in admixture with a carrier as specified in the ’086 patent. Elysium represents to the public that each capsule of BASIS® comprises microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica.

57. BASIS® is formulated for oral administration.

58. On information and belief, Elysium has been, and is still, knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the ’086 patent, including at least claim 2, by making, having made, using, selling, having sold, offering to sell, and/or importing the BASIS® product in or into the United States, without authority. Thus, Elysium is liable for its infringement of the ’086 patent in violation of 35 U.S.C. §271(a).

59. On information and belief, Elysium has been, and is still, knowingly and

intentionally inducing infringement, literally and/or under the doctrine of equivalents, of one or more claims of the ’086 patent, including at least claim 2, by actively encouraging others to make, have made, use, offer for sale, sell, have sold, and/or import the BASIS® product in or into the United States, without authority. For example, on information and belief, Elysium has actively and knowingly encouraged and facilitated, and continues to actively and knowingly encourage and facilitate, others to directly infringe the ’086 patent including at least claim 2, by instructing, directing, and/or advising others how to administer and use BASIS®. Thus, Elysium is liable as an active inducer of infringement of the ’086 patent in violation of 35 U.S.C. § 271(b).

60. On information and belief, Elysium has been, and is still, knowingly and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the ’086 patent, including at least claim 2, by making, having made, using, selling, having sold, offering to sell and/or importing the BASIS® product in or into the United States, without authority. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that the BASIS® product is especially made or adapted for use in an infringement of the ’086 patent, that the BASIS® product includes a material component for use in practicing the ’086 patent, and that the BASIS® product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Elysium is liable for its infringement of the ’086 patent in violation of 35 U.S.C. § 271(c).

61. On information and belief, Elysium’s infringement of the ’086 patent has been willful, intentional, and deliberate. On information and belief, Elysium is and has been aware of the ’086 patent and knows that the BASIS® product falls within the claims of the ’086 patent. Elysium knew or should have known of the ’086 patent at least as early as February 2014. At

that time, it entered into a Supply Agreement and Trademark License and Royalty Agreement with ChromaDex, both of which related to ChromaDex's NIAGEN® and made reference to the '086 patent. As recently as 2017, Elysium continued to mark its BASIS® product with the '086 patent, showing an awareness that the '086 patent covered its BASIS® product. Healthspan has also provided notice to Elysium of the '086 patent by marking the TRU NIAGEN® dietary supplements that it obtains from ChromaDex pursuant to 35 U.S.C. § 287(a). Third parties who formulate dietary supplements under their own label using NIAGEN® obtained from ChromaDex, also provide notice to Elysium of the '086 patent by marking those dietary supplements pursuant to 35 U.S.C. § 287(a). In addition, the filing of this Complaint constitutes actual notice to Elysium of the '086 patent under 35 U.S.C. § 287.

62. Plaintiffs have been damaged by the infringing acts of Elysium and will continue to be damaged unless this Court enjoins Elysium from these actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor and against Elysium, granting the following relief:

(a) Declaring that Elysium has directly infringed, contributorily infringed, and induced infringement of, and is continuing to directly infringe, contributorily infringe, and induce infringement of, one or more claims of the '807 and '086 patents;

(b) Permanently enjoining Elysium, together with its directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliates, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from directly or indirectly infringing the '807 and '086 patents;

(c) Awarding Plaintiffs damages adequate to compensate for Elysium's infringing activities, including lost profits, but in no event less than a reasonable royalty, in accordance with 35 U.S.C. § 284, including supplemental damages for any post-verdict infringement up until entry of final judgment with an accounting, as needed, together with pre-judgment and post-judgment interest on the damages awarded;

(d) Declaring that Elysium's infringement has been willful, and awarding enhanced damages under 35 U.S.C. § 284;

(e) Finding that this case is exceptional under 35 U.S.C. § 285, and awarding ChromaDex and Dartmouth their attorneys' fees incurred in connection with this action; and

(f) Awarding Plaintiffs such other and further relief as this Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a trial by jury of all issues so triable.

Dated: September 17, 2018

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